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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,563	07/16/2003	Satoshi Kidooka	P23565	7116

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RESTON, VA 20191

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/04/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No. 10/619,563	Applicant(s) KIDOOKA, SATOSHI	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9,12-17,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,12-17,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 6, 2006 has been entered. In particular, applicant's amendments have obviated the objection to claims 11 and 18.

Claim Rejections - 35 USC § 103

Claims 1-3, 5-9 and 12-17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi (2002/0123667) in view of Rydell (5,035,696) and further in view of the teaching of Weaver et al (5,536,248).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Ouchi discloses a bipolar treatment tool for an endoscope substantially as set forth in the instant application claims. It includes a flexible insulating tube (102) made of PTFE (col. 3, line 13); an end effector (110,112) attached to the end of the tube and a pair of conductive wires (122,124) extending through the tube and coupled to the end effector to provide bipolar energy to the individual jaws. The examiner maintains that the use of any well known insulating material, including a silicone resin, for making the flexible tube is deemed an obvious design consideration for one of ordinary skill in the

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art. Slater et al also disclose a proximal operating portion (Figure 1) for actuating the pair of conductive wires to operate the end effector . The only features not taught by Ouchi is the provision of two generally circular channels in the insulating tube through which the wires are individually passed. Rather, Ouchi provides a single channel and passes both wires through the single channel, each wire provided with its own individual insulation sheath.

Rydell also discloses a flexible, bipolar tool for an endoscope. In particular, Rydell teaches that the two conductive wires (24,26) may be individually insulated and passed through a lumen in the flexible insulating tube (see Figure 1). Alternatively, Rydell also teaches that the wires may be uninsulated and the flexible insulating sheath may be provided with two channels for housing the wires individually and obviate the need for an insulation coating on the wires (see Figure 5 and col. 5, lines 10-19). The Rydell lumens are semi-circular in shape. The examiner maintains that the use of any shaped lumen in a catheter device would be an obvious design consideration for one of ordinary skill in the art.

In support of this assertion, Weaver et al disclose another flexible electrosurgical tool for an endoscope very much like the Rydell device. In particular, Weaver et al provide lumens in the flexible body for the passage of various instruments and devices, including electrode leads. Of particular note, Weaver et al teach of the well-known use of variously shaped lumens for providing advantageous characteristics, such as diminished cross sectional area, for the flexible member. Figures 12 and 12a of the Weaver et al device show the use of circular-shaped lumens, and Figures 19-24 show

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various other configurations including combinations of circular and semi-circular shaped lumens to maximize lumen surface area. In column 10, lines 18-35, Weaver et al specifically disclose that the various alternative lumen shapes are deemed obvious alternatives. The examiner maintains that the size of the lumens and the separation of the lumens disclosed by Weaver et al are for the specific micro-endoscopic device, and one of ordinary skill in the art would recognize acceptable size ranges for lumens and the separation of lumens in any device.

To have provided the Ouchi flexible tube with two channels for providing the individual conductive wires and obviating the need for insulation coatings on the individual wires would have been an obvious alternative arrangement for one of ordinary skill in the art, particularly since Rydell teach that providing two channels in an insulating tube is a known alternative to insulated wires being passed through a single lumen in an insulating tube. To have further provided the two channels as two circular lumens to more fittingly receive the leads would have been an obvious design consideration for one of ordinary skill in the art in view of the Weaver et al patent which teaches that such alternative lumen shapes are generally well known and obvious alternatives.

Claims 1-3, 5-7 and 12-17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al (5,482,054) in view of Rydell (5,035,696) and further in view of the teaching of Weaver et al (5,536,248).

Slater et al discloses a bipolar treatment tool for an endoscope substantially as set forth in the instant application claims. It includes a flexible insulating tube (50,300)

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made of poly-ethylene (col. 5, line 42), an end effector (18) attached to the end of the tube and a pair of conductive wires (60) extending through the tube and coupled to the end effector to provide bipolar energy to the individual jaws. The examiner maintains that the use of any well known insulating material, including a silicone resin, for making the flexible tube is deemed an obvious design consideration for one of ordinary skill in the art. The only feature not taught by Slater et al is the provision of two generally circular channels in the insulating tube through which the wires are individually passed. Rather, Slater et al provide a single channel and passes both wires through the single channel, each wire provided with its own individual insulation sheath.

Rydell also discloses a flexible, bipolar tool for an endoscope. In particular, Rydell teaches that the two conductive wires (24,26) may be individually insulated and passed through a lumen in the flexible insulating tube (see Figure 1). Alternatively, Rydell also teaches that the wires may be uninsulated and the flexible insulating sheath may be provided with two channels for housing the wires individually and obviate the need for an insulation coating on the wires (see Figure 5 and col. 5, lines 10-19). The Rydell lumens are semi-circular in shape. The examiner maintains that the use of any shaped lumen in a catheter device would be an obvious design consideration for one of ordinary skill in the art.

In support of this assertion, Weaver et al disclose another flexible electrosurgical tool for an endoscope very much like the Rydell device. In particular, Weaver et al provide lumens in the flexible body for the passage of various instruments and devices, including electrode leads. Of particular note, Weaver et al teach of the well-known use

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of variously shaped lumens for providing advantageous characteristics, such as diminished cross sectional area, for the flexible member. Figures 12 and 12a of the Weaver et al device show the use of circular-shaped lumens, and Figures 19-24 show various other configurations including combinations of circular and semi-circular shaped lumens to maximize lumen surface area. In column 10, lines 18-35, Weaver et al specifically disclose that the various alternative lumen shapes are deemed obvious alternatives. The examiner maintains that the size of the lumens and the separation of the lumens disclosed by Weaver et al are for the specific micro-endoscopic device, and one of ordinary skill in the art would recognize acceptable size ranges for lumens and the separation of lumens in any device.

To have provided the Slater et al flexible tube with two channels for providing the individual conductive wires and obviating the need for insulation coatings on the individual wires would have been an obvious alternative arrangement for one of ordinary skill in the art, particularly since Rydell teach that providing two channels in an insulating tube is a known alternative to insulated wires being passed through a single lumen in an insulating tube. To have further provided the two channels as two circular lumens to more fittingly receive the leads would have been an obvious design consideration for one of ordinary skill in the art in view of the Weaver et al patent which teaches that such alternative lumen shapes are generally well known and obvious alternatives.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al (5,482,054), Rydell (5,035,696) and Weaver et al (5,536,248) as applied to the above claims, and further in view of the teaching of Sutton et al (5,762,613).

Slater et al provides a clevis attachment at the distal end of the device to operate the jaws, but fails to specifically disclose a pair of pins, each pin supporting a separate jaw as recited in claims 8 and 9. Rather, Slater et al provides a single insulative pin (28) upon which both jaws are connected.

Sutton et al disclose a similar device that includes a flexible tubular member (22) with a pair of control wires extending therethrough and connected to jaws (80,81) of an end effector. In particular, Sutton et al teach that the distal end of the device may include a clevis having two separate pins (72,73) with each jaw member connected to a separate pin to allow individual actuation of the jaw members.

To have provided the Slater et al device, as modified by the prior art teachings, with a dual pin clevis construction to allow for the individual actuation of the jaw members would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sutton et al (5,762,613).

Response to Arguments

Applicant's arguments filed December 6, 2006 have been fully considered but they are not persuasive.

Applicant first asserts that the Rydell conductive wire (26) cannot contain insulation to perform its intended use (page 7 of the response). This simply is not true.

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Rydell explicitly disclose at column 5, lines 10-18 that the conductive wire may be provided with insulation except for its exposed active portion. Alternatively, the wire may be uncoated if provided in separate channels. Applicant's assertion that there is no reason to make the connecting wire bare is clearly unfounded in view of this very explicit teaching of Rydell. The examiner stands by the reasoning that this disclosure of Rydell would suggest to one of ordinary skill in the art that devices that have multiple insulated wires may obvious provide the wires in an uninsulated manner if provided in separate lumens of the device. It is noted that the fact that the "operative portion" of the Rydell wire must be exposed has no bearing on the examiner's rejection. Clearly it must be uncoated, but clearly Rydell teach that the remainder of the wire may either be provided uninsulated in its own lumen, or insulated along its length except for the operative portion.

Next, applicant argues that Ouchi and Slater et al do not use bare conductive wires as their operative element. Again, this does not matter, nor is it entirely true. Each of Ouchi and Slater et al provides multiple, insulated wires through a single lumen of a tube. Each wire in the Ouchi and Slater et al devices has an exposed operative portion that is connected to the jaw member. Clearly, both Ouchi and Slater et al do disclose wires insulated along their lengths with bare operative portions for delivery of electrical energy. See Figure 1 of the Ouchi patent and Figure 7 of the Slater et al patent for the depiction of the bare "operative portion" of the wire. There is as much need for Slater et al and Ouchi to have an exposed portion of wire as there is for Rydell,

for if the Ouchi and Slater et al wires were entirely insulated, there would be no electrical connection to the jaw members.

Applicant has also traversed the examiner's assertion that any shape lumen may be used in a catheter device as an obvious design consideration, and that an assertion of obvious design consideration is not the proper evidentiary standard necessary to support a rejection under 35 U.S.C 103. The examiner disagrees. Applicant's specification is void of any criticality or unexpected result associated with the shape of the lumens. Moreover, the examiner has clearly provided the necessary evidentiary support by showing that it is known in the prior art to use various lumen shapes in order to accommodate various lumens in a more compact or rigid arrangement. That the Weaver lumens are not of a size commensurate with that now disclosed in the claims is immaterial. The examiner is not suggesting the Weaver device be used to accommodate the wires of the Ouchi or Slater et al devices because that would be impossible. Ouchi and Slater et al are larger devices for endoscopic deployment. Weaver discloses a device seeking to minimize the cross section of an endoscopic device for use in very small areas. One of ordinary skill in the art would recognize that the Weaver teaching of providing lumens in a wide variety of shapes would apply to any endoscopic device regardless of the size. There is always a need to provide numerous lumens through an endoscopic device whether the device has a diameter of 10 French or 1 French, and Weaver shows an acceptable number of ways to arrange lumens, including lumen shapes, in order to accommodate the various lumens in the device. Such a teaching clearly applies to endoscopic devices of all sizes, and one of ordinary

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skill in the art would clearly recognize that the Weaver et al lumen sizes and separation distances are a result of the remarkably small configurations necessary for the Weaver procedure, and that they are not meant as limiting to all applications of the lumen arrangements.

The examiner maintains that applicant's arguments are not persuasive, and that the claims remain unpatentable for the reasons set forth above.

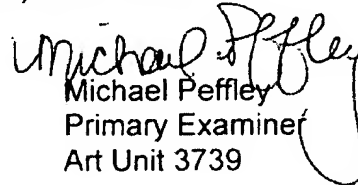
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
December 20, 2006